



1560

1614A  
PATENT

Practitioner's Docket No. U-013469-7

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: **BONNIE M. DAVIS**

Application No.: 09/856,282

Group No.: 1614

Filed: JUNE 18, 2001

Examiner: JONES, DWAYNE, C.

For: **DOSAGE FORMULATIONS FOR ACETYLCHOLINESTERASE INHIBITORS**

**Commissioner for Patents**

**P. O. Box 1450**

**Alexandria, VA 22313-1450**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING DATE OF EITHER A FINAL ACTION  
OR NOTICE OF ALLOWANCE (37 C.F.R. 1.97(c))**

**NOTE:** 37 C.F.R. 1.97: "(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

- (1) The statement specified in paragraph (e) of this section; or
- (2) The fee set forth in § 1.17(p)."

**NOTE:** "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. 1.8(a)**

**37 C.F.R. 1.10\* (Preferred)**

☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"  
Mailing Label No. \_\_\_\_\_ (mandatory)

**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office. to **(571)-273-8300**

Date: September 19, 2006

09/25/2006 EEKUBAY1 00000012 09856282

01 FC:1806

180.00 DP

Signature

JOHN RICHARDS

(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** 37 C.F.R. § 1.704(d): "A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable."

**NOTE:** "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final. Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

**WARNING:** No extension of time can be had under 37 C.F.R. 1.136(a) or (b) for filing an IDS. 37 C.F.R. 1.97(f).

### **TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed **after** three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,

whichever occurs first.

### **STATEMENT OR FEE**

2. Accompanying this transmittal is  
(check either A or B below)

A. ☐ a statement as specified in 37 C.F.R. 1.97(e).

**OR**

B. ☒ the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

### **METHOD OF PAYMENT OF FEE**

- 3.

- ☒ Attached is a check in the amount of \$ 180.00.  
☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.  
A duplicate of this request is attached.

If any additional or lesser fees are due, please charge or refund deposit Account 12-0425.

Reg. No.

**JOHN RICHARDS**  
c/o LADAS & PARRY  
Tel. No.: ( ) 26 WEST 61st STREET  
NEW YORK, N.Y. 10023  
Reg. No. 31053 (212) 708-1916  
Customer No.:

  
SIGNATURE OF PRACTITIONER

JOHN RICHARDS  
(type or print name of practitioner)

P.O. Address

c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Bonnie M. Davis

Serial No.: 09/856,282

Group No.: 1614

Filed: June 18, 2001

Examiner: Jones, Dwayne C.

For: Dosage Formulations for Acetylcholinesterase Inhibitors

Attorney Docket No.: U013469-7

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Upon checking the PAIR site in preparation for an interview on June 20, it was noted that several documents which our file shows to have been enclosed with various responses do not appear to be in the PTO file. This Information Disclosure Statement is to make formal submission of those documents.

Respectfully submitted,

  
\_\_\_\_\_  
John Richards  
LADAS & PARRY  
26 West 61st. Street  
New York, New York 10023  
Reg. 31053  
Tel. (212) 708-1915

---

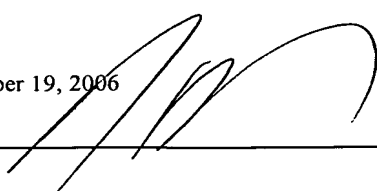
**CERTIFICATE OF MAILING/TRANSMISSION (37 CFR 1.8a)**

I hereby certify that this correspondence is, on the date shown below, being:

deposited with the United States Postal Service  
with sufficient postage as first class mail in an  
envelope addressed to the Commissioner for  
Patents, P. O. Box 1450, Alexandria, VA 22313-  
1450

Date: September 19, 2006

Signature

  
\_\_\_\_\_  
John Richards  
(type or print name of person certifying)

FORM PTO-1449

U. S. DEPARTMENT OF  
COMMERCE  
PATENT AND TRADEMARK  
OFFICE

ATTY. DOCKET NO.

SERIAL NO.

**U013469-7****09/856,282**

APPLICANT

**BONNIE M. DAVIS**

FILING DATE

GROUP

**June 18, 2001****1614**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIALS | REFERENCE<br>DESIGNATION | DOCUMENT<br>NUMBER | DATE | NAME | FILING DATE IF<br>APPROPRIATE |
|----------------------|--------------------------|--------------------|------|------|-------------------------------|
|                      | AA                       |                    |      |      |                               |
|                      | AB                       |                    |      |      |                               |
|                      | AC                       |                    |      |      |                               |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT<br>NUMBER | DATE | COUNTRY | TRANSLATION |    |
|--|----|--------------------|------|---------|-------------|----|
|  |    |                    |      |         | YES         | NO |
|  | AD |                    |      |         |             |    |
|  | AE |                    |      |         |             |    |
|  | AF |                    |      |         |             |    |

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

|  |    |   |
|--|----|---|
|  | AG | Circadian Rhythms and Drug Deliver - Journal of Controlled Release, 16 (1991) 63-74   |
|  | AH | Sensitive Liquid Chromatographic Method for Physostigmine in biological fluids using dual-electrode electrochemical Detection - Robin Whelpton & Thomas Moore - Journal of Chromatography 341 (1985) 361-371  |
|  | AI | Physician Desk Reference, Antivert, Pfizer/2665-2667  |
|  | AJ | A 1-year, placebo-controlled preservation of function survival study of donepezil in AD patient - R. C. Mohs, PhD, Neurology 57 - pgs.481-486   |
|  | AK | Psychotropics - Terminal Plasma half-lives -Eptastigmine tartrate   |
|  | AL | Psychotropics - Terminal Plasma half-lives -Tacrine   |
|  | AM | Pub Med - J. Clin Pharmacol, 1989 Mar 29(3) 278-84 - Single dose safety, tolerance and pharmacokinetics of HP 092 in healthy young men: a potential Alzheimer agent - Pur SK, Hsu RS, Ho I, Lassman HB  |
|  | AN | Pub Med - J. Clin Pharmacol, 1990 Oct 30(10) 948-55 - Multiple dose pharmacokinetics, safety, and tolerance of velnarine (HP029) in healthy elderly subjects: a potential therapeutic agent for Alzheimer's disease - Puri SK, Ho I, Hsu R, Lassman HB  |
|  | AO | Pub Med - Expert Opin Invest Drugs 1999 Apr 8(4) 463-71-Metrifonate (Trichlorfon): a review of the pharmacology, pharmacokinetics and clinical experience with a new acetylcholinesterase inhibitor for Alzheimer's disease. - Ringman JM, Cummings, JL |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

|  |                                  |  |                        |                   |                                       |
|--|----------------------------------|--|------------------------|-------------------|---------------------------------------|
| <b>FORM PTO-1449</b> <b>U. S DEPARTMENT OF<br/>COMMERCE<br/>PATENT AND TRADEMARK<br/>OFFICE</b><br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use several sheets if necessary)                                       |                                  | <b>ATTY. DOCKET NO.</b>  |                        | <b>SERIAL NO.</b> |                                       |
|  |                                  | <b>U013469-7</b>   |                        | <b>09/856,282</b> |                                       |
|  |                                  | <b>APPLICANT</b>   |                        |                   |                                       |
|  |                                  | <b>BONNIE M. DAVIS</b>   |                        |                   |                                       |
|  |                                  | <b>FILING DATE</b>   |                        | <b>GROUP</b>      |                                       |
|  |                                  | <b>June 18, 2001</b>   |                        | <b>1614</b>       |                                       |
| <b>U.S. PATENT DOCUMENTS</b>   |                                  |  |                        |                   |                                       |
| <b>EXAMINER<br/>INITIALS</b>   | <b>REFERENCE<br/>DESIGNATION</b> | <b>DOCUMENT<br/>NUMBER</b>   | <b>DATE</b>            | <b>NAME</b>       | <b>FILING DATE IF<br/>APPROPRIATE</b> |
|  | AA                               |  |                        |                   |                                       |
|  | AB                               |  |                        |                   |                                       |
|  | AC                               |  |                        |                   |                                       |
| <b>FOREIGN PATENT DOCUMENTS</b>  |                                  |  |                        |                   |                                       |
|  |                                  | <b>DOCUMENT<br/>NUMBER</b>   | <b>DATE</b>            | <b>COUNTRY</b>    | <b>TRANSLATION</b><br>YES      NO     |
|  | AD                               |  |                        |                   |                                       |
|  | AE                               |  |                        |                   |                                       |
|  | AF                               |  |                        |                   |                                       |
| <b>OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)</b>  |                                  |  |                        |                   |                                       |
|  | AG                               | Razadyne galantamine HBr - pgs 1-6   |                        |                   |                                       |
|  | AH                               | Fluoride Action Network Pesticide Project-Adverse Effects methanesulfonyl fluoride - Cas No. 558-25-8  |                        |                   |                                       |
|  | AI                               | Calbiochem - Phenylmethylsulfonyl Fluoride - Cat. No. 52332  |                        |                   |                                       |
|  | AJ                               | Pub Med. J. Microencapsul. 2005 Feb 22(1) 57-66 - Effects of formulation factors on encapsulation efficiency and release behaviour in vitro of huperzine A-PLGA microspheres - Fu X, Ping Q, Gao Y |                        |                   |                                       |
|  | AK                               | GPnotebook - Endrophonium test   |                        |                   |                                       |
|  | AL                               | Effects of Novel Cholinesterase inhibitors based on the mechanism of enzyme inhibition - Albert Enz, Dieter Meier and Rene Spiegel   |                        |                   |                                       |
|  | AM                               | Journal of Chromatography 272 (1983) 216-220 - Analysis of plasma physostigmine concentrations by liquid chromatography - Robin Whelpton   |                        |                   |                                       |
|  | AN                               | Arch Neurol/vol 58, Mar 2001 - Open-Label, Multicenter, phase 3 extension study of the safety and Efficacy of Donepezil in Patients with Alzheimer Disease - Rachelle S. Doody MD -p. 427-433      |                        |                   |                                       |
|  | AO                               | The Effects of Donepezil in Alzheimer's Disease-Results from a Multinational Trial - Dermert Geriatr Cogn Disord 1999; 10: 237-244 - A. Burns  |                        |                   |                                       |
| <b>EXAMINER</b>  |                                  |  | <b>DATE CONSIDERED</b> |                   |                                       |
| <b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                                  |  |                        |                   |                                       |

|   |                          |   |                 |            |                               |
|---|--------------------------|---|-----------------|------------|-------------------------------|
| FORM PTO-1449 U. S DEPARTMENT OF<br>COMMERCE<br>PATENT AND TRADEMARK<br>OFFICE<br><br>INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br><br>(Use several sheets if necessary)   |                          | ATTY. DOCKET NO.  |                 | SERIAL NO. |                               |
|   |                          | U013469-7   |                 | 09/856,282 |                               |
|   |                          | APPLICANT   |                 |            |                               |
|   |                          | BONNIE M. DAVIS   |                 |            |                               |
|   |                          | FILING DATE   |                 | GROUP      |                               |
|   |                          | June 18, 2001   |                 | 1614       |                               |
| U.S. PATENT DOCUMENTS   |                          |   |                 |            |                               |
| EXAMINER<br>INITIALS  | REFERENCE<br>DESIGNATION | DOCUMENT<br>NUMBER  | DATE            | NAME       | FILING DATE IF<br>APPROPRIATE |
|   | AA                       |   |                 |            |                               |
|   | AB                       |   |                 |            |                               |
|   | AC                       |   |                 |            |                               |
| FOREIGN PATENT DOCUMENTS  |                          |   |                 |            |                               |
|   |                          | DOCUMENT<br>NUMBER  | DATE            | COUNTRY    | TRANSLATION                   |
|   |                          |   |                 |            | YES NO                        |
|   | AD                       |   |                 |            |                               |
|   | AE                       |   |                 |            |                               |
|   | AF                       |   |                 |            |                               |
| OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)  |                          |   |                 |            |                               |
|   | AG                       | International Journal of Chronobiology, Vol. 2, 281-289 (1974) - Circadian Variations of Acetylcholinesterase (E.C.3.1.1.7) in Rats Brains O H. Schiebeler and H. v. Mayersbach                                       |                 |            |                               |
|   | AH                       | Neuroscience Letters 300 (2001) 157-160 - Differential increase in cerebrospinal fluid-acetylcholinesterase after treatment with acetylcholinesterase inhibitors in patients with Alzheimer's disease - Pia Davidsson |                 |            |                               |
|   | AI                       | Brain Research, 122 (1977) 562-267 - The time-dependent induction of REM sleep and arousal by physostigmine infusion during normal human sleep - Natarajan Sitaram  |                 |            |                               |
|   | AJ                       | JAGS - Jan. 1998 - Vol. 46, No. - p. 119-120-Aricept-induced nightmares in Alzheimer's Disease  |                 |            |                               |
|   | AK                       |   |                 |            |                               |
|   | AL                       |   |                 |            |                               |
|   | AM                       |   |                 |            |                               |
|   | AN                       |   |                 |            |                               |
|   | AO                       |   |                 |            |                               |
| EXAMINER  |                          |   | DATE CONSIDERED |            |                               |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                          |   |                 |            |                               |